

002780-48422960

CLAIMS

1. A stable granulocyte colony-stimulating factor-containing formulation comprising a granulocyte colony-stimulating factor and at least one pharmaceutically acceptable surfactant in an amount of 1 part by weight or less per part by weight of the granulocyte colony-stimulating factor and having a pH of 7 or less.
2. The granulocyte colony-stimulating factor-containing formulation of Claim 1 wherein the surfactant is contained in an amount ranging from 0.2 to 1 parts by weight per part by weight of the granulocyte colony-stimulating factor.
3. The granulocyte colony-stimulating factor-containing formulation of Claim 2 wherein the surfactant is contained in an amount ranging from 0.2 to 0.8 parts by weight per part by weight of the granulocyte colony-stimulating factor.
4. The granulocyte colony-stimulating factor-containing formulation of Claim 2 wherein the surfactant is contained in an amount ranging from 0.4 to 0.8 parts by weight per part by weight of the granulocyte colony-stimulating factor.
5. The granulocyte colony-stimulating factor-containing formulation of Claim 2 wherein the surfactant is contained in an amount of 0.4 or 0.8 parts by weight per part by weight of the granulocyte colony-stimulating factor.
- ~~6. The granulocyte colony-stimulating factor-containing formulation of Claim 1, which is substantially free from protein as a stabilizer.~~
7. The granulocyte colony-stimulating factor-containing formulation of Claim 1 wherein the surfactant is at least

one member selected from the group consisting of nonionic surfactants such as sorbitan fatty acid esters, glycerin fatty acid esters, polyglycerin fatty acid esters, polyoxyethylene sorbitan fatty acid esters, polyoxyethylene sorbitol fatty acid esters, polyoxyethylene glycerin fatty acid esters, polyethylene glycol fatty acid esters, polyoxyethylene alkyl ethers, polyoxyethylene polyoxypropylene alkyl ethers, polyoxyethylene alkyl phenyl ethers, polyoxyethylene hardened castor oils, polyoxyethylene beeswax derivatives, polyoxyethylene lanolin derivatives, polyoxyethylene fatty acid amides; cationic surfactants such as alkyl sulfates, polyoxyethylene alkyl ether sulfates, alkyl sulfosuccinic acid ester salts; and natural surfactants such as lecithin, glycerophospholipids, sphingophospholipids, sucrose fatty acid esters.

8. The granulocyte colony-stimulating factor-containing formulation of Claim 1 wherein the surfactant is a polyoxyethylene sorbitan fatty acid ester selected from the group consisting of Polysorbate 20 and Polysorbate 80.

~~9. The granulocyte colony-stimulating factor-containing formulation of Claim 1, which has a pH of 5-7.~~

~~10. The granulocyte colony-stimulating factor-containing formulation of Claim 1, which has a pH of 6-6.8.~~

11. The granulocyte colony-stimulating factor-containing formulation of Claim 1, which has a pH of 6.2-6.8.

12. The granulocyte colony-stimulating factor-containing formulation of Claim 1, which is packed in a vial, ampoule or prefilled syringe.